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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,090	05/04/2001	Kevin G. Hetzler	P-5263	9400

26253 7590 05/19/2004

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EXAMINER
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CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/849,090	<b>Applicant(s)</b> HETZLER, KEVIN G.	
	<b>Examiner</b> MONZER R CHORBAJI	<b>Art Unit</b> 1744	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

**This non-final office action is in response to the remarks received on 02/24/2004**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui (JP 11152355).

With respect to claims 1, 9, and 14, Mitsui teaches a method of terminally sterilizing pre-filled syringes (page 1, example) including the following: pre-filled syringes (page 8, technical field, lines 9-10 such that pre-filled syringes inherently means that such syringes have been filled with a liquid and sealed) that have already been filled with a liquid (this step is equivalent to filling the syringes), heating the pre-filled syringes in an autoclave (technical field, page 7, paragraph 0071, lines 3-5) in the presence of steam. Mitsui teaches in paragraphs 0071-0074 to first heat the syringes using steam whose temperature normally is 80 degree Celsius or greater, which is equivalent to a first temperature greater than 100 degree Celsius such that the processing time is 5 minutes or more, which is equivalent for at least 30 minutes (paragraphs 0071-0074). Then Mitsui teaches to maintain the syringes at a second temperature higher than (T-20) degrees Celsius at a reduced relative humidity of 50% or 20% or even less (this is equivalent to reducing the humidity). For example, if the temperature of the steam, which is T, is 110

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degrees Celsius then the second temperature is (110-20) degrees Celsius, which is 90 degrees Celsius and is less than 100 degree Celsius and greater than 80 degree Celsius. Thus the first temperature is reduced to the second temperature. This temperature is equivalent to the second temperature. Also, Mitsui teaches that the time range in this second step is 20 minutes or more. This time represents the time in the second treatment step.

With respect to claims 2-8, 10-13, and 15-20, Mitsui discloses the following: heating the syringe at the second temperature in a dry atmosphere (paragraphs 0071-0074) heating the syringe in the autoclave to a first temperature between 120 and 130 degree Celsius (paragraphs 0071-0074) and then reducing the temperature to a second temperature and maintaining for at least 30 minutes in a dry atmosphere (paragraphs 0071-0074), second temperature is between 80 and 120 degree Celsius (paragraphs 0071-0074), removing the syringes from the autoclave and transferring the syringes to an oven having a relatively dry atmosphere (paragraphs 0071-0074) and maintaining the second temperature between 80 and 120 degree Celsius for at least 40 minutes (paragraphs 0071-0074), and maintaining the second temperature at a reduced relative humidity of less than 50 percent (even reducing the humidity to 20% or less).

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

On page 2 of the response, applicant argues, "applicant submits that Matsui does not disclose a step of reducing the temperature of said syringe assembly to

a second temperature of between 80 degree Celsius and less than 100 degree Celsius and maintaining said second temperature for at least 20 minutes". The examiner disagrees. Mitsui teaches in paragraphs 0071-0074 to first heat the syringes using steam whose temperature normally is 80 degree Celsius or greater, which is equivalent to a first temperature greater than 100 degree Celsius such that the processing time is 5 minutes or more, which is equivalent for at least 30 minutes (paragraphs 0071-0074). Then Mitsui teaches to maintain the syringes at a second temperature higher than  $(T-20)$  degrees Celsius at a reduced relative humidity of 50% or 20% or even less (this is equivalent to reducing the humidity). For example, if the temperature of the steam, which is  $T$ , is 110 degrees Celsius then the second temperature is  $(110-20)$  degrees Celsius, which is 90 degrees Celsius and is less than 100 degree Celsius and greater than 80 degree Celsius. Thus the first temperature is reduced to the second temperature. This temperature is equivalent to the second temperature. Also, Mitsui teaches that the time range in this second step is 20 minutes or more. This time represents the time in the second treatment step (paragraphs 0071-0074).

On page 3 of the response, applicant argues, "Matsui does not teach or suggest reducing the humidity of said cyclic olefin container or delivery device and maintaining a second temperature less than 120 degree Celsius, as recited by claim 14". The examiner disagrees. In paragraphs 0071-0074, Mitsui teaches reducing relative humidity of 50% or 20% or even less (this is equivalent to reducing the humidity) and to maintain the syringes at a second temperature higher than  $(T-20)$  degrees Celsius. For example, if the temperature of the steam, which is  $T$ , is 110 degrees Celsius then the second

temperature is (110-20) degrees Celsius, which is 90 degrees Celsius and is less than 120 degree Celsius and greater than 80 degree Celsius. This temperature is equivalent to the second temperature. Also, Mitsui teaches that the time range in this second step is 20 minutes or more. This time represents the time in the second treatment step (paragraphs 0071-0074).

On page 3 of the response, applicant argues, "Matsui does not disclose reducing the humidity, as recited by applicant's claim. Matsui merely discloses providing an atmosphere of 50% or less of relative humidity". The examiner disagrees. In paragraphs 0071-0074, Mitsui teaches reducing the relative humidity to 50% and even teaches reducing the humidity further to 20% or even reducing it to less than 20%. This is equivalent to reducing the humidity step in the instant claims.

### ***Conclusion***

4. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Jurgens, Jr. et al (U.S.P.N. 4,628,969), Liebert et al (U.S.P.N. 5,207,983), and Liebert et al (U.S.P.N. 5,256,154) teach similar concepts in sterilizing syringes using steam.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji *MRC*  
Patent Examiner  
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05/14/2004

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